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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/807,643	03/23/2004	Aaron V. Kaplan	015471-000910US	3899

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EXAMINER

SCHILLINGER, ANN M

ART UNIT	PAPER NUMBER
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3738

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/807,643

Applicant(s)

KAPLAN ET AL.

Examiner

Ann Schillinger

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 December 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 23-61 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 23-61 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/29/2006.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

Claims 24-31, 33-45, 47-55, and 58-61 are objected to because of the following informalities: the claims use an indefinite article, when a definite article should be used to begin these dependent claims. Appropriate correction is required.

Double Patenting

Claims 23, 24, 25, 29, 32, 36, 37, 56, 57, 58, 59, 60, and 61 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 2, 30, 5, 33, 34, 16, 37, 40, 41, 41, 42, and 36 respectively of copending Application No. 11/076448. Although the conflicting claims are not identical, they are not patentably distinct from each other because both sets of claims a prosthesis comprising a radially expandable support and a plurality of anchors that are expandable and configured to be positioned across the os and into the main body lumen of a blood vessel.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

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Claims 23, 24, 27-30, 32-37, 39, 41-43, 45-47, 49, 50, and 52-61 are rejected under 35 U.S.C. 102(e) as being anticipated by Solovay (U.S. Pat. No. 6,482,227). Solovay discloses the following of claim 23: a prosthesis for placement at an os opening from a main body lumen to a branch body lumen; the main body lumen having a main vessel wall with a portion of the main vessel wall opposing the os, said prosthesis comprising: a radially expansible scaffold (30; col. 5, lines 28-29) having at least a first wall pattern (11, 30); and at least two circumferential anchors (80(a), 80(b), 40) extending axially from an end of the scaffold, said anchors adapted having sufficient length to extend axially into and expandably circumscribe at least the main vessel wall and reach the portion of the main vessel wall opposing the os when the scaffold is implanted in the branch lumen with said one end adjacent the os (see Figure 19), said prosthesis additionally having a region with a second wall pattern (60, 43A, 43B) that is different from the first wall pattern (see Figure 15), said second wall pattern permitting the anchors to both bend and rotate relative to the prosthesis (see Figure 19).

Solovay discloses the following of claim 24: a prosthesis as in Claim 23, comprising at least three circumferential anchors (40) extending axially from the end of the scaffold (see Figure 15).

Solovay discloses the following of claim 27: a prosthesis as in Claim 23, wherein the scaffold comprises a plurality of axially adjacent cells (col. 3, lines 58-63).

Solovay discloses the following of claim 28: a prosthesis as in Claim 23, wherein the circumferential anchors are all congruent (see Figure 19).

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Solovay discloses the following of claim 29: a prosthesis as in Claim 23, wherein the circumferential anchors will radially expand when the scaffold is radially expanded (col. 7, line 67 through col. 8, line 1).

Solovay discloses the following of claim 30: a prosthesis as in Claim 23, further comprising a radiopaque marker (15) at or near the region with the second wall pattern (see Figure 3).

Solovay discloses the following of claim 32: a method for deploying a prosthesis across an Os opening from a main lumen to a branch lumen, the main body lumen having a main vessel wall with a portion of the main vessel wall opposing the os, said method comprising: positioning a first prosthesis (30) so that a scaffold lies within the branch lumen (see Figure 19) and at least two circumferential anchors (80(a), 80(b), 40) extend into the main lumen; radially expanding the scaffold to implant said scaffold in the branch lumen (col. 5, lines 28-29); circumferentially deforming the anchors such that at least one of said anchors bends and rotates relative to the prosthesis (see Figure 19), and has sufficient length to reach the portion of the main vessel wall opposing the os (see Figure 19), said deforming causing the anchors to circumscribe at least a portion of the main lumen wall (shown above element 30 in Figure 19) and open a passage through the anchors; and deploying a second prosthesis within the passage through the anchors (col. 7, lines 37-39).

Solovay discloses the following of claim 33: a method as in Claim 32, wherein at least three circumferential anchors (40) extend into the main lumen (see Figure 15).

Solovay discloses the following of claim 34: a method as in Claim 32, wherein positioning the first prosthesis comprises aligning a visible marker on at least one of the prosthesis and a delivery balloon with the Os (col. 2, lines 61-66).

Solovay discloses the following of claim 35: a method as in Claim 32, wherein the lumens are blood vessels (col. 5, lines 25-26).

Solovay discloses the following of claim 36: a method as in Claim 32, wherein the scaffold is expanded with a balloon expanded within the scaffold (col. 2, line 61 through col. 3, line 8).

Solovay discloses the following of claim 37: a method as in Claim 36, wherein the anchors are deformed by expanding a balloon positioned transversely through the anchors (col. 2, line 61 through col. 3, line 8).

Solovay discloses the following of claim 39: a method as in Claim 37, wherein the scaffold and anchors are expanded and deformed by different balloons (col. 3, lines 1-5).

Solovay discloses the following of claim 41: a method as in Claim 32, wherein the anchors are deformed by deployment of the second prosthesis (col. 7, lines 34-39).

Solovay discloses the following of claim 42: a method as in Claim 32, wherein the deployed second prosthesis supports the anchors over their lengths from the Os over the main lumen wall (col. 11, lines 9-16).

Solovay discloses the following of claim 43: a prosthesis as in Claim 23, mounted on a balloon catheter (col. 2, lines 61-66).

Solovay discloses the following of claim 45: a prosthesis as in Claim 23, comprising at least five anchors (40; see Figure 15).

Solovay discloses the following of claim 46: a prosthesis for placement at an os opening from a main body lumen to a branch body lumen, the main body lumen having a main vessel wall with a portion of the main vessel wall opposing the os, said prosthesis comprising: a radially expansible scaffold (30; col. 5, lines 28-29) having at least a first wall pattern (11, 30); and at least one anchor (80(a), 80(b), 40) extending from an end of the scaffold, said anchor having a length sufficient to circumscribe the main vessel wall and reach the portion of the main vessel wall opposing the os when the scaffold is implanted in the branch lumen with said one end adjacent the os (see Figure 19).

Solovay discloses the following of claim 47: a prosthesis as in Claim 46, wherein the anchor extends helically from the scaffold (see Figure 19).

Solovay discloses the limitations of claims 49 and 50 as shown in Figures 15 and 19.

Solovay discloses the limitations of claims 52 and 53 in element 15 and col. 7, lines 6-7.

Solovay discloses the limitations of claims 54 and 55 in col. 2, lines 61-66.

Solovay discloses the following of claim 56: a method for deploying a prosthesis across an Os opening from a main lumen to a branch lumen, the main body lumen having a main vessel wall with a portion of the main vessel wall opposing the os, said method comprising: positioning a first prosthesis (30) so that a scaffold lies within the branch lumen (see Figure 19) and at least two anchors (80(a), 80(b), 40) extend into the main lumen; radially expanding the scaffold to implant said scaffold in the branch lumen (col. 5, lines 28-29); circumferentially deforming the anchors such that at least one of said anchors extends along the main vessel wall a sufficient distance to reach the portion of the main vessel wall opposing the os (see Figure 19).

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Solovay discloses the following of claim 57: a method of positioning a prosthesis across the ostium opening between a main vessel and a branch vessel, the main vessel extending in both an upstream direction and a downstream direction from the ostium, comprising the steps of: providing a radially expandable scaffold (30; col. 5, lines 28-29), having a first end (lower end of element 30) and a second end (upper end of element 30) and at least three anchors (80(a), 80(b), 40) extending from the first end (see Figure 19); and positioning the prosthesis such that the scaffold is within the branch vessel and the anchors extend along the wall of the main vessel and all point in an upstream direction (see Figure 19).

Solovay discloses the limitations of claims 58-60 in col. 2, line 61 through col. 3, line 8.

Solovay discloses the following of claim 61: a method as in Claim 57, comprising entrapping the anchors against the wall of the main vessel using a main vessel stent (col. 7, lines 42-45).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 26, 44, 48, and 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay in view of Chobotov et al. (U.S. Pub. No. 2003/0125797). Solovay discloses the invention substantially as claimed, however, Solovay does not disclose the lengths of the anchors as being greater than at least 2 mm or 6mm. Chobotov et al. teaches the lengths of the anchors as being greater than at least 2 mm or 6 mm in paragraph 0125 for the purpose of enabling the

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prosthesis to treat a larger range of patients. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to make the lengths of the anchors greater than at least 2 mm or 6 mm in order to enable the prosthesis to treat a larger range of patients.

Solovay discloses the limitations of dependent claim 51 in Figures 15 and 19.

Claim 31 is rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay in view of Sheiban (U.S. Pat. No. 5,226,889). Solovay discloses the invention substantially as claimed, however, Solovay does not disclose placing a radiopaque marker on the balloon being used to expand the prosthesis. Sheiban teaches placing a radiopaque marker on the balloon being used to expand the prosthesis for the purpose of allowing the surgeon to view the position of the prosthesis with a fluoroscope. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to place a radiopaque marker on the balloon being used to expand the prosthesis in order to allow the surgeon to view the position of the prosthesis with a fluoroscope.

Claims 38 and 40 are rejected under 35 U.S.C. 103(a) as being unpatentable over Solovay in view of Imran et al. (U.S. Pat. No. 6,241,744). Solovay discloses the invention substantially as claimed, however, Solovay does not disclose using only one balloon to deploy on the anchors of the prosthesis. Imran et al. teaches using only one balloon to deploy on the anchors of the prosthesis for the purpose of decreasing implantation time. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to use only one balloon to deploy on the anchors of the prosthesis in order to decrease implantation time.

Response to Arguments

Applicant's arguments with respect to claims 23-61 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ann Schillinger whose telephone number is (571) 272-6652. The examiner can normally be reached on Mon. thru Fri. 9 a.m. to 4 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Ann Schillinger
February 27, 2007

A. Stewart
ALVIN J. STEWART
PRIMARY EXAMINER